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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,079	02/16/2000	Joni Kristin Doherty	49321-1A	5713

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EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/506,079

Applicant(s)

DOHERTY ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,8-10,18-20 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,8-10,18-20 and 38-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. The amendment filed August 18, 2003 is acknowledged. Claims 4-7, 11-17 and 21-37 were canceled. Claims 38-41 were added. Claims 1-3, 8-10, 18-20 and 38-41 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Objections and Rejections Withdrawn:***

3. The objection to the disclosure because it contains an embedded hyperlink and/or other form of browser-executable code is withdrawn upon further consideration.

The objection to claims 9 and 10 for depending from claim 6, is withdrawn in view of the amendments to claims 9 and 10.

4. Applicant's submission of new drawings is acknowledged. The objection to the drawings are removed.

5. The rejection of claims 1-3, 9, 10 and 18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

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6. In view of the amendment to the claims, wherein the provision is added that the scope of the claims specifically exclude SEQ ID NO: 11 or SEQ ID NO: 12, the following two rejections, and the provisional double patenting rejection are withdrawn. However, should the claims be amended to include the subject matter of SEQ ID NO: 11, or SEQ ID NO: 12, then these rejections will be reinstated.

7. The rejection of claims 1-3, 8-10 and 18-20 under 35 U.S.C. 102(e) as being anticipated by Doherty et al (U.S. Patent 6,414,130; issued July 2, 2002; effective filing date of Jan. 20, 1999) is withdrawn in view of the amendment to the claims.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Doherty discloses polypeptides comprising SEQ ID NO: 1 or SEQ ID NO: 2, where the SEQ ID NO: 1 or SEQ ID NO: 2 of Doherty are species of the SEQ ID NO: 1 or SEQ ID NO: 2 of the instant application (see abstract and col. 2, lines 41-50, col. 3, lines 1-12, col. 3 line 52 – col. 4, line 5; sequence listing, col. 19-col. 25). Thus, Doherty discloses the claimed inventions.

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8. The rejection of claims 1-3 and 8-10 under 35 U.S.C. 102(a) as being anticipated by Doherty et al (Doherty et al, Proc. Nat. Acad. Sci., USA, 96(19): 10869-10874, 1999, Sep.) is withdrawn in view of the amendments to the claims.

Doherty(PNAS) teaches Herstatin, which is a sequence that comprises 79 amino acids of SEQ ID NO: 1 and 300 amino acids of SEQ ID NO: 2. Doherty(PNAS) teaches that Herstatin may be glycosylated. Thus, Doherty(PNAS) teaches the claimed inventions.

9. The provisional rejection of claims 1-3, 8-10 and 18-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 8-10 and 18-22 of copending Application No. 09/234,208 is withdrawn in view of the amendment to the claims.

10. The rejection of claims 1, 3, 18 and 19 under 35 U.S.C. 102(b) as being anticipated by Greene et al (U.S. Patent 5,464,751; issued Nov. 7, 1995) is withdrawn in view of the amendment of the claims.

11. The rejection of claims 1, 3, 10, 18 and 19 under 35 U.S.C. 102(b) as being anticipated by Wels et al (U.S. Patent 5,571,894; issued Nov. 5, 1996) is withdrawn in view of the amendment of the claims.

12. The rejection of claims 1, 3, 8, 10, 18 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Ring (U.S. Patent 6,054,561; issued Apr. 25, 2000; filing date June 7, 1995) is withdrawn in view of the amendment of the claims.

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***Claim Rejections Maintained and New Grounds of Rejection:***

13. The rejection of claims 1-3, 8-10 and 18-20 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. New grounds of rejection are presented. **This rejection is applied to new claims 38-41.**

The basis for this rejection is that the disclosure of the specification fails to describe the subgenus of compounds encompassed by the claims, where the subgenus is defined to exclude SEQ ID NO: 11 or SEQ ID NO: 12, or a fragment of SEQ ID NO: 11 that is 50-79 contiguous residues in length, or a fragment of SEQ ID NO: 12 that is 80-419 contiguous residues in length.

The claims as currently amended and new claims 38-41 claim a subgenus of polypeptides that exclude sequences disclosed in the prior art. The amendment fails to point to support for such a subgenus of polypeptides, and an inspection of the specification fails to reveal that applicant contemplated such a subgenus at the time of filing. Therefore, the amendment to the claims and the addition of new claims 38-41 constitutes new matter.

14. The rejection of claim 18 under 35 U.S.C. 102(e) as being anticipated by Hudziak (U.S. Patent 6,399,063; issued June 4, 2002; effective filing date Jan. 25, 1988) is maintained for the reasons of record.

Claim 18 recites pharmaceutical compositions that comprise an agent that is a monoclonal antibody that binds to the extracellular domain of Her-2 in combination with at least a second agent. Hudziak discloses pharmaceutical compositions comprising an antibody to Her-

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2 and a second agent, such as a cytokine (TNF-alpha, TNF-beta, IL-2, IL-2, Interferon-gamma; see col. 7, lines 3 – 61; claims 8-13). Thus, Hudziak discloses the claimed pharmaceutical compositions.

Applicant's arguments have been carefully considered, but are unpersuasive. Applicant appears to be arguing that the claims read on monoclonal antibody combinations with second agents, where the second agent may only be one of items "a" or "b", as recited in the claim. However, such an interpretation is too narrow. As claim 18 currently reads, it is drawn to a pharmaceutical agent that is either "a", "b", or "c + any second agent", because of the proviso that the agent may not be "the monoclonal antibody alone". Item "c" is "a monoclonal antibody that binds to the extracellular domain of Her-2". The proviso language does not limit the second agent to either the agent of "a" or "b". Therefore, Hudziak disclosure reads on the claimed pharmaceutical agents, because Hudziak teaches pharmaceutical compositions that are combination of an antibody that binds to the extracellular domain of Her-2 in combination with a second agent.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran  
Patent Examiner  
October 6, 2003

  
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